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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,942	01/23/2002	Maurice Zauderer	1821.0090004	1028
26111	7590	06/02/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			PONNALURI, PADMASHRI	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,942

Applicant(s)

ZAUDERER ET AL.

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 4, 9-19, 21-45, and 48-58 drawn to a method of selecting polynucleotides of first library (i.e., see step e), classified in class 435, subclass 6.
 - II. Claims 2-3, 9-19, 21-45, drawn to a method of selecting polynucleotides of first library (uses the polynucleotides identified in group I), classified in class 435, subclass 6.
 - III. Claims 5, 9-45, drawn to a method of selecting polynucleotides of the second library (uses the polynucleotides identified in group II method), classified in class 435, subclass 6.
 - IV. Claims 6-19, 21-45, drawn to a method of selecting polynucleotides of the second library (uses the polynucleotides identified in group III method), classified in class 435, subclass 6.
 - V. Claim 46, drawn to a method for constructing a first library of polynucleotides, classified in class 435, subclass 69.1.
 - VI. Claim 47, drawn to a method for constructing a second library of polynucleotides, classified in class 435, subclass 69.1.
 - VII. Claims 59-65, drawn to a method, where each of said first library further comprises a heterologous polynucleotide (i.e., fusion protein or conjugate), classified in class 435, subclass 69.7.
 - VIII. Claim 66, drawn to a kit for the identification of an intracellular immunoglobulin molecule, classified in class 435, subclass 810.

- IX. Claims 67-68, drawn to an intracellular immunoglobulin, classified in class 530, subclass 387.1.
- X. Claims 69-71, 74-78, drawn to a method of selecting polynucleotides which encode a single chain intracellular immunoglobulin comprising heavy chain variable region, classified in class 530, subclass 387.3.
- XI. Claims 72-73, drawn to a method of selecting polynucleotides which encode a single chain intracellular immunoglobulins (using the polynucleotides identified in group X method), classified in class 530, subclass 387.3.
- XII. Claim 79, drawn to a method of selecting polynucleotides which encode a single chain intracellular immunoglobulin comprising heavy chain variable region and light chain variable region, classified in class 530, subclass 387.3.
- XIII. Claim 80, drawn to a method of selecting polynucleotides which encode a single chain intracellular immunoglobulin comprising heavy chain variable region and Leucine Zipper, classified in class 435, subclass 69.7.
- XIV. Claim 81, drawn to a kit for identification of polynucleotide encoding single chain immunoglobulin, classified in class 435, subclass 801.
- XV. Claims 83-84, drawn to a single chain intracellular immunoglobulin, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions of groups I-VII, X-XIII are all drawn to patentably distinct methods. The different methods of groups I-VII and X-XIII are not disclosed as capable of use together and

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they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the group I methods are drawn to a method of identifying polynucleotides encoding polynucleotides of first library; group II method uses the first library polynucleotides to identify the polynucleotides of the first library (see step j); group III uses the polynucleotides of the first library identified in the group II method to identify polynucleotides of group III method; group IV uses the polynucleotides of the second library identified in the group III method to identify polynucleotides of group IV method; group V is method for synthesis of the first library, which is different from the group VI method of synthesis of second library; and group VII method differs from the group V method by the different components; and group X methods are drawn to selecting the single chain immunoglobulins with heavy chain; the XI methods uses the polynucleotides identified in group X method; group XII method is drawn to selecting a single chain immunoglobulin comprising heavy chain and light chain; group XIII method is drawn to selecting single chain immunoglobulin comprising heavy chain and leucine zipper. Thus, all the disclosed methods are distinct and are not used together and the end result are not the same. Thus, restriction between different methods is proper.

3. Inventions of groups VIII, IX, XIV, XV are all drawn to different products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of different products, group VIII is drawn to a kit for identification of intracellular immunoglobulin; and group IX is drawn to intracellular immunoglobulin; and group XIV is drawn to a kit for identification of the single chain immunoglobulin; and group XV is drawn to single chain intracellular immunoglobulin.

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The different products as claimed are not capable of use together, have different modes of operation and different functions. Thus, the restrictions between the products is proper.

4. Inventions of the method groups and product groups are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of products are not used in any of the claimed methods, and the products have different have different functions compare to the claimed methods, and the modes of operation of the methods are different; and the products can be identified by several different claimed methods (practiced by different methods); and the kits claimed can be used in any of the claimed methods. Thus, restriction between the groups of products and processes as claimed are distinct and restriction is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: the following election of species is required:

- a) a single species of eukaryotic virus vector (i.e., claims 30-34);
- b) a single species of naturally occurring genome (i.e., claims 27-28);
- c) a single species of promoter;
- d) a single species of modified phenotype;
- e) a single species of heterologous polypeptide.

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Because the claimed different species are distinct from each other and are not capable of use together, the species election between the species is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-17, 20-23, 29, 39-41, 46-47, 53-54, 60, 66-84 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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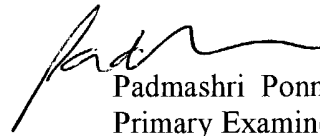
7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
01 June 2004